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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,692

12/11/2003

Philip Stashenko

25669-003

4324

7590 04/25/2011
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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

04/25/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,692	Applicant(s) STASHENKO ET AL.	
	Examiner GYAN CHANDRA	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27-29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27-29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2011 has been entered.

Status of Application, Amendments, And/Or Claims

The amendments of claims 1, 27-29 and 31-33 have been made of record.
Claims 1, 27-29 and 31-33 are pending and under examination.

Response to Arguments

Claim Rejections - 35 USC § 112-written description-withdrawn

The rejection of claims 1, 27-29 and 31-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants' amendments to the claims.

Claim Rejections - maintained

Claim Rejections - 35 USC § 112-scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 27-29 and 31-33 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting OC14 protein in a bone cell by administering an antibody that decreases an activity of said protein, does not reasonably provide enablement for a method of inhibiting osteoclast-mediated bone resorption in a bone cell (in vitro or in vivo) comprising administering any antibody that inhibits OC14 protein activity for the reasons discussed below.

Applicants argue (see Response of 3/23/2011) that the claimed invention is on the basis that the expression of OC14 is up-regulated during RANKL-induced osteogenesis. They argue that the inventors are the first to identify that osteoclast-mediated bone resorption can be inhibited by decreasing the expression of a gene product encoded by the osteoclast-related gene OC14. They argue that the subject matter pending is described in the specification, e.g., at pages 1-2, 49 and 58. They argue that the specification discloses that decreasing the expression of a gene product encoded by OC14 will inhibit osteoclast-mediated bone resorption and that the inhibition of the gene product is by OC14 antibody.

Applicants' arguments have been fully considered but they are not persuasive because the specification discloses that MIP-1 gamma or RANKL stimulates osteoclast differentiation (Figures 4A, 4B, 5A-5B, 6 or 7) but the specification fails to disclose any example where OC14 activates bone resorption or an antibody against OC14 inhibits bone resorption. The invention is based on the presumption that since OC14 gene is up-regulated upon a bone cell treatment with MIP-1 gamma then the inhibition of OC14 should play a role in bone resorption. The specification on pages 1-2, 49 and 58

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discloses, in general, regarding gene expression and how one of the skill in the art could make and use an antibody to inhibit a protein activity. The specification discloses the sequence for OC14 and therefore, at best one of the skill in the art can make the protein and an antibody against the protein encoded by OC14. Additionally, using the antibody one of the skill in the art can inhibit OC14 gene encoded protein. But one of the skill in the art will not be able to predict, without undue experimentation, if the antibody against protein encoded by OC14 gene can inhibit bone resorption in any bone cell which reads on in vivo treatment. Additionally, the specification does not disclose a nexus between any OC14 encoded protein and the osteoclast mediated bone resorption. Applicant may present further data and publications to show that an antibody against a protein encoded by OC14 inhibits bone resorption. Therefore, it is unpredictable and would require undue experimentation from the skilled artisan to practice the claimed invention in its full scope.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/
Primary Examiner, Art Unit 1646